UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader
January 15, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

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MEMORANDUM

DATE: 6 /23/98

SUBJECT: HED OCCUPATIONAL AND RESIDENTIAL EXPOSURE CHAPTER FOR THE PROPETAMPHOS RED (ID#113601-002724)

DP Barcode:	D239321	PRAT Case#:	816422
Submission#:	S527692	Caswell#:	None
Chemical#:	113601	Class:	INSECTICIDE
		Trade Names:	Safrotin EC, Zoecon RF-256 Aerosol, Zoecon 8718 EW, Zoecon 9001 EW

TO: Elizabeth Doyle, Branch Chief
CEB1/HED (7509C)

FROM: Steven H. Weiss, Industrial Hygienist
RAB2/HED (7509C)

THRU: Richard Loranger, Branch Senior Scientist
RAB2/HED (7509C)

1. A copy of the HED occupational and residential exposure chapter for the propetamphos Registration Eligibility Decision (RED) is enclosed with this memo. Per your request the document was done in a “stream-line” RED format.

2. Questions or comments should directed to Mr. Steven Weiss, Industrial Hygienist at (703) 308-8293.

Propetamphos
Streamline RED Format
Occupational and Residential Summary Sheet

Chemical Number: 113601

This is a screening level assessment; therefore HED has provided a brief overview of the registered uses and potential occupational and residential exposure scenarios. If risks were acceptable for several of the exposure scenarios, HED would need to refine this assessment to more completely define the uses and actual exposure scenarios.

I. SUMMARY OF TOXICOLOGY ENDPOINT SELECTION (HIARC 4/29/98)

The doses and toxicological endpoints selected for various exposure scenarios are summarized below.

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary	NOEL 0.05	Brain cholinesterase inhibition	Mouse 4-Week Oral Toxicity
Chronic Dietary non-carcinogenic effects	NOEL=0.05 (UF=100)	Decreased brain, RBC, and plasma cholinesterase	Mouse Chronic Toxicity/Carcinogenicity
		Chronic RfD = 0.0005 mg/kg/day	
Chronic Dietary carcinogenic effects		To be determined after Cancer Assessment Review Commiteee meeting	
Short-Term* (Dermal)	NOEL = 0.08	RBC cholinesterase inhibition	6-Month -Dog
Intermediate-Term* (Dermal)			
Chronic Dermal* non-carcinogenic effects			
Chronic Dermal* carcinogenic effects		To be determined after Cancer Assessment Review Commiteee meeting	
Inhalation (Any Time Period)	**LOEL 0.027 mg/L	plasma cholinesterase inhibition.	

* Since an oral NOEL was selected a 100% dermal absorption factor should be used for this risk assessment

**The inhalation NOEL was converted from a concentration (0.027 mg/L) to a dose (mg/kg/day) as follows:

$$\frac{0.027\ \text{mg/L} * 10.3\ \text{L/hour (Sprague-Dawley rat inhalation rate)} * 4\ \text{hr/day (rat exposure duration)}}{0.236\ \text{kg (Sprague-Dawley rat body weight)}}$$

= 4.7 mg/kg/day

II. Exposure Characterization

Occupational workers are potentially exposed to propetamphos from the application of the following four registered products:

- Safrotin Emulsifiable Concentrate Insecticide
- Zoecon RF-256 Aerosol
- Zoecon 8718 EW
- Zoecon 9001 EW

These insecticide products are applied in concentrations of 0.5 % to 1.0% active ingredient as liquids or as an aerosol spray. They may be applied as broadcast, crack/crevice, gallery (injection for termites), and/or spot applications. The four products labels indicate that they may only be applied by professional certified operators (PCOs). Therefore, it is assumed that homeowners would not be applying any of these products. However, these products are registered for application use in homes (applied by PCOs). Therefore post-application exposure for children and adults may occur.

III. Occupational Exposure Assessment

1. The following assumptions and considerations were used for assessing occupational exposure to propetamphos:

- Application Rates

For applications using Zoecon RF-256 Aerosol, a commercial applicator is assumed to apply a maximum of ten 16 oz cans /day (0.1 lb ai/day).

For broadcast and crack/crevice applications, a commercial applicator was assumed to handle 1.3 lb ai/day. For gallery treatment (injection for termites), a commercial applicator was assumed to handle 8.2 lb ai/day.

These rates are based on the HED memo, *Documentation of Applicator Exposure Assessment for Re-registration Eligibility Document - Application in the Residential Environment (dated 6/10/96)*. Chlorpyrifos has similar application scenarios and concentrations of active ingredient.

The amount of active ingredient handled per day may be higher for some registered use sites listed in REFS which include:

* Ships, boats, and ship holds (site code 70004)

* Food processing handling and storage plants/areas (site code 71000)
* Food marketing, storage and distribution facilities (site code 73000)
* Hospitals and related institutions (site code 74000)
* Commercial or institutional areas/premises (site code 77000)
* Commercial storage or warehouses (site code 77004)

- Application Scenarios

The application scenarios used in this assessment (aerosol can for crack and crevice, broadcast/crack and crevice using low-pressure hand-wand, and gallery applications) are considered to be typical for commercial applicators.

2. A summary of exposure estimates and risk assessments for occupational handlers is included as **Table 1.** HED's worker exposure estimates are based on surrogate data from the Pesticide Handlers Exposure Database (PHED) and/or the Best Available Surrogate Exposure Table (BASET, 5/97).

a. DERMAL - Dermal MOEs calculated for workers wearing the minimum level of PPE (long sleeve shirt, long pants, gloves, and shoes) for aerosol can application, low-pressure hand wand , and gallery application are 0.5, 6.3, and 1 respectively. Generally MOEs less than 100 exceed HED's level of concern. If workers wear coveralls, MOEs would increase to 0.7, 7.4 and 2 respectively which still exceeds HED's level of concern. Long sleeve shirt, long pants, gloves, shoes, and coveralls are considered the maximum level of PPE in regard to dermal exposure for these application scenarios. Use of engineering controls such as closed mixing systems were not considered practical or feasible for these scenarios.

b. INHALATION - Inhalation MOEs calculated for workers wearing the minimum level of PPE (long sleeve shirt, long pants, gloves, and shoes) exceed 300 for all scenarios.

IV. Home-owner Applicator Exposure Assessment

Products containing protamphos may only be applied by PCOs. It is assumed that homeowners will not be mixing or applying products containing propetamphos.

Table 1. Occupational Handler Exposure Estimate and Risk Assessment Summary										
		DERMAL						INHALATION		
		(with Minimum PPE)[a]			(with coveralls)[b]					
Application Scenario	(lb ai/day)	UE[c] (mg/lb ai)	ADD[d] (mg/kg/day)	MOE[e]	UE (mg/lb ai)	ADD[c] (mg/kg/day)	MOE[d]	UE (mg/lb ai)	ADD[c] (mg/kg/day)	MOE[d]
Aerosol Can (crack and crevice) Application	0.10	66.4	0.095	0.8	50.3	0.072	1.1	2.43	0.0035	1300
Low-Pressure Handwand Mixer/Loader/Applicator (broadcast & crack and crevice)	1.3	0.427	0.0079	10	0.36	0.0067	12	0.03	0.00056	8400
Gallery (termite injection) Mixer/Loader/Applicator	8.2	0.359	0.042	2	0.247	0.03	3	0.0022	0.00026	18000

[a] The minimum PPE is long sleeve shirt, long pants, shoes, socks and gloves

[b] The addition of coveralls provides a 50% reduction of dermal exposure to the body (does not include head & neck)

[c] Unit Exposure (UE) is value from the Pesticide Handlers Exposure Database (PHED) and/or the Best Available Surrogate Exposure Table (BASET, 5/97)

[d] ADD(mg/kg/day) = [PHED unit exposure(mg/lb ai) * Amount handled (mg ai handled/day)] / 70 kg by wt

[e] MOE = NOEL/ADD (where dermal NOEL = 0.08 mg/kg/day and inhalation NOEL = 4.7 mg/kg/day)

V. Residential Post-Application Exposure Assessment

Indoor Application to Indoor Carpets and Hard Surfaces

A residential post application exposure estimate and risk assessment was conducted for the application of propetamphos on indoor carpet and hard surfaces using the SOPs for Residential Exposure Assessments (12/18/97) and is summarized in **Tables 2 and 3**. The following considerations and assumptions were used:

* Application Rate (AR) of 0.0027 lb ai/ft^2 was used. The AR was derived from the label for Safrotin EC Insecticide (EPA Reg No.2724-314). The density of formulation was not given on label. Therefore, the density of water was assumed for converting volume in fluid ounces to lb ai.

1 gal /1,500 ft^2 (AR from label) * 0.5 (% ai)* 128 oz/1gal * 1 lb/16 fl oz = 0.0027 lb ai/ft^2

* The mean dermal transfer coefficient is assumed to be 43,000 for Adults and 8,700 cm^2/hr for toddlers.

* It is assumed that an average of 50 percent of the application rate (from broadcast or crack and crevice treatments) is available on the carpet as dislodgeable residue (U.S. EPA, 1993).

* Postapplication exposure was assessed on the same day the pesticide was applied since it is assumed that homeowners could contact the treated carpet immediately after application.

* The duration of exposure is assumed to be 8 hours per day for carpet and 4 hours for hard surfaces.

* The SOPs Residential Exposure Assessments rely on high-end scenarios and should be considered conservative estimates. These scenarios normally rely on one or more upper-percentile assumptions such as the 90th percentile exposure duration values and/or 90th percentile skin surface area values. They are intended to represent Tier 1 assessments. If a Tier 1 assessment indicates a potential concern, a more detailed exposure assessment is warranted, possibly including chemical-specific or site-specific data.

When using the SOPs for Residential Exposure Assessments, the post-application Dermal MOEs were less than 1 for all scenarios addressed.

Table 2. Postapplication Exposure Estimates and Risk Assessments									
Scenario	Receptor	AR[a] (lb ai/ft^2)	ISRt (ug/cm^2)	Tc (ug/cm^2)	ET (hrs)	Surface Area (cm^2/event)	Frequency (events/hr)	ADD[e] (mg/kg/day)	MOE
Dermal Exposure from Treated Carpet	Toddler (15 kg)	0.0027	660	8,700	8	-	-	3071	2.6×10^{-5}
	Adult (70 kg)	0.0027	660	43,000	8	-	-	3253	2.5×10^{-5}
Dermal Exposure from Treated Hard Surfaces	Toddler (15 kg)	0.0027	660	8,700	2	-	-	1536	5.2×10^{-5}
	Adult (70 kg)	0.0027	660	43,000	2	-	-	1626	4.9×10^{-5}
Hand-to-mouth Exposure for Treated Carpet or Hard Surfaces	Toddler (15 kg)	0.0027	660	-	2	350	1.56	48	5.2×10^{-4}

[a]AR, Application Rate =
ISRt, Indoor surface residue (ug/cm^2) = [AR, Application Rate (lbs ai/ft^2) * fraction ai retained on surface (50%) * 4.54E+8 ug/lb * 1.08E-03 ft^2/cm^2]
Tc, Transfer Coefficient
ET, Exposure Time
ADD, Average daily dose (mg/kg/day):
Dermal = [ISRt (ug/cm2) * Tc (cm^2/hr) * mg/1,000 ug * ET (hrs/day) * absorption factor (1.0)] / [BW (kg)]
Hand-to-mouth = [ISRt (ug/cm2) * SA (350 cm2/event) * FQ (1.56 events/hr) * mg/1,000 ug * ET (2 hrs/day)] / [BW (kg)]

[f]MOE = NOEL/ ADD (where Dermal NOEL = 0.05 mg/kg/day and Acute Dietary NOEL = 0.05 mg/kg/day)

*Default assumptions are from HED's SOPs for Residential Exposure Assessments, 12/18/97

Chemical Specific Postapplication Studies

A post-application study for propetamphos on indoor carpet (MRID431908) was performed in February 1993 and submitted to the agency. A 0.5% Safrotin solution was applied to six unfurnished hotel rooms. Individuals performed Jazzersize activities during the sampling period. A review of the study was performed by Paladin Associates, Inc. (under contract to Versar, Inc -Contract No. 68-D3-0133). They concluded that the following five Subdivision K guidelines were not met:

* The site at which the study was conducted must possess a climate similar to those in which the product was to be used.

* The study must include meteorological data at or near the location of the test site.

* Sampling intervals must be short at first and may subsequently increase.

* The storage stability, method efficiency for each collection matrix, and quantitation limit must be provided.

* At least one field fortification sample per worker per monitoring period per fortification level must be generated for each matrix. There must be at least one field blank per worker per monitoring for each matrix.

The remaining 10 of 15 the Subdivision K guidelines were met. A summary of the study review performed by Versar is included as Attachment (1).

The dermal, inhalation, and oral ADDs and MOEs were calculated using the results from the indoor carpet postapplication study and are summarized in **Table 4.** All dermal MOEs are less than 1. Inhalation MOEs range from 32,000 to 51,000. The oral MOE for toddlers weighing 15 kg is 9.

Table 4. Postapplication Exposure and Risk Assessment from Safrotin Carpet Study						
	Dermal		Inhalation		Oral	
	ADD[a] (μg/kg/day)	MOE[c]	ADD[a] (μg/kg/day)	MOE[c]	ADD[a] (μg/kg/day)	MOE[c]
Adult	92.8	0.5	1.48	3200	0.650	77
Toddler (10.5 kg)	115	0.4	1.31	3600	8.06	6
Toddler (15 kg)[b]	80.5	0.6	0.917	5100	5.64	9

[a]ADD from this study were based on the following defaults/assumptions:
Average male body surface area is 21,100 cm^2
Adult breathing rate is 18.4 m^3 of air /24 hrs for adults and 3.1 m^3 of air /24 hrs for children
Adult body weight is 70kg and child is 10.5 kg.
Inhalation percent absorption is 60%

[b]ADD from study was adjusted to a 15 kg bodyweight. This is the current weight used for toddlers by HED.

[c]MOE= NOEL/ADD where Dermal NOEL= 0.05 mg/kg/day, Inhalation NOEL= 4.7 mg/kg/day, Acute Dietary NOEL= 0.027 mg/kg/day

TERMITICIDE POSTAPPLICATION EXPOSURE

The Multi-Chamber Concentration and Exposure Model (MCCEM), as outlined in the SOPs for Residential Exposure Assessments (12/18/97), was used to estimate post application inhalation exposures for occupants after the injection of 8.2 lb ai in the foundation of a home. The following assumptions and considerations were used:

- Adults are assumed to weigh 70. Toddlers (3 years old), used to represent the 1 to 6 year old age group, are assumed to weigh 15 kg.
- A mean inhalation rate of 13.3 m^3/day for adults and 8.7 m^3/day for toddlers was used to calculate daily exposures.
- Five percent of termiticides applied by foundation/soil injection techniques penetrate the foundation of a house to become a source for offgassing in a Chinn type emission. This is based on the experience and professional judgement of the OPP staff based on the review of company-submitted data. All termiticides applied indoors are assumed to be 100 percent available for emission.

The inputs used for this assessment are summarized in Table 5.

Table 5. Scenarios and Input Parameters for *MCCEM*

Use Scenario	House Type & Season	Air Exchange Rate (xch/hr)	Chamber Type (Number Zones)	Model Type	Calculation Duration (days)	Emission Type	Emission Rate	Product Use Scenario	Room of Use	*MCCEM* Decay Rate
Termiticides	Generic/ Summer	0.18	Single (1)	Long-Term	365	Chinn Evaporation	Chinn Rate	Entire House and 5 % Penetration Inside	Bedroom	0.00

Chinn Release Emission Rate Calculations:

er = m/d
er = emission rate in grams/hr
m = mass of ai in grams

$d = 145 /((MW*VP)^{0.9546})$
d = Chinn evaporation time (hrs)
MW = molecular weight of ai
vp = Vapor Pressure of ai

m = (8.2 lbs ai)* (454 g/lb) = 3722.8 g
d = $145/(281.3 \text{ g/mole})*(0.005 \text{ torr})^{0.9546} = 201$ hrs
er = 3722.8/201 = 18.52 g/hr

ADD and MOE Calculations:

$ADD = (C_a * IR)/BW$

ADD = Average Daily Dose (mg/day)
C_a = modeled airborne concentration of pesticide in air (5.8 mg/m^3)
IR = inhalation rate (m^3/day)
BW = body weight (kg)

Toddlers: **ADD** = (5.8 mg/m^3)*(8.7 m^3/day)/15 kg = **3.36 mg/kg/day**

MOE = $\frac{\text{NOEL}}{\text{ADD}} = \frac{\text{4.7 mg/kg/day}}{\text{3.36 mg/kg/day}}$ **= 1.4**

Adults: **ADD** = (5.8 mg/m^3)*(13.3 m^3/day)/70 kg = **1.10 mg/kg/day**

MOE = $\frac{\text{NOEL}}{\text{ADD}} = \frac{\text{4.7 mg/kg/day}}{\text{1.10 mg/kg/day}}$ **= 4.3**

The inhalation postapplication MOEs for toddlers and adults are 1.4 and 4.3 respectively.